

Exhibit 5

VIRGINIA

IN THE CIRCUIT COURT FOR THE CITY OF ROANOKE

SHARON G. WINGATE,)
EXECUTOR OF THE ESTATE OF)
DOUGLAS GRAY WINGATE, DECEASED)
)
Plaintiff,)
)
v.) Case No. CL12-2547
)
INSIGHT HEALTH CORP.,)
JOHN MATHIS, M.D.,)
ROBERT F. O'BRIEN, M.D.,)
And)
IMAGE GUIDED PAIN MANAGEMENT,)
P.C.)
)
Defendants.)

MEMORANDUM OF LAW IN SUPPORT OF THE REPLY OF INSIGHT HEALTH CORP.

COMES NOW, Defendant INSIGHT HEALTH CORP. ("IHC"), by and through counsel, Bonner Kiernan Trebach & Crociata, LLP, and hereby submits this Reply Memorandum of Law in Support of its previously filed Demurrer to the Plaintiff's Complaint filed on or about January 24, 2013 and in Reply to Plaintiff's Opposition to the Demurrer.

INTRODUCTION

This case is one of many lawsuits filed around the country that involves persons who were injected with contaminated steroids that were manufactured and sold by the New England Compounding Center a/k/a New England Compounding Pharmacy ("NECC") and were injured or even worse, as here. Plaintiff's husband, who was a patient of defendants Dr. Mathis and/or Dr. O'Brien, received an injection of a contaminated steroid from NECC and, tragically, later died. None of the defendants had any way of knowing that the steroids NECC provided were contaminated. Her complaint includes more than 45 paragraphs solely

about NECC. However, plaintiff failed to name NECC as a defendant to this lawsuit. Moreover, Plaintiff filed her complaint only six days after NECC filed for bankruptcy. Plaintiff's counsel also knew or should have known NECC had filed for bankruptcy protection at the time they filed the Complaint. In fact, Plaintiff is a creditor in the NECC bankruptcy proceeding. Plaintiff's counsel also knew or should have known that most, if not all of the other meningitis cases involving contaminated steroids manufactured and sold by NECC from around the country, are now part of a multi-district litigation panel through which all cases and discovery concerning NECC must flow. (*See* MDL 2419.) Plaintiff's counsel knew or should have known all that. But that's precisely why they did not name NECC in its complaint. They know that if they named NECC as a defendant in this case, then they would have had to deal with the necessary and the appropriate procedural steps in order to properly proceed with its case -- for instance, file motions to lift the stay in the bankruptcy proceeding, file motions and seek discovery from NECC through the MDL proceeding, exactly what all of the other plaintiffs in similar meningitis cases just like this one will likely have to do in order to properly proceed with their cases.

Rather than do that, however, Plaintiff simply chose to omit NECC from the case and now contends that it the Defendants' problem. That is not fair and just. And that is precisely why the rule exists that a failure to name a necessary and indispensable party in a complaint is grounds for dismissing an action. Couched as either a plea in bar, or a demurrer, Plaintiff's failure to name NECC as a defendant renders her complaint it is defective. If there are not sufficient parties to the instant action such that complete relief can be afforded among the parties, like here, then any such complaint is defective, and must be remedied in order for the case to move forward.

The only reason why IHC has filed Rule 1:9 motions regarding a third-party complaint or crossclaims is because, under the Rules, there is only 21 days in which to file any such pleading after the filing of a responsive pleading, and that time period would expire before there would be a ruling on its Demurrer. It is not an admission or remedy as Plaintiff's suggest. Quite the contrary, IHC has only done so in order to preserve the right to seek to file such claims -- in the event that it even becomes necessary.

In short, whether the Court treats Defendant IHC's responsive pleading as demurrer or plea in bar, as co-defendants Image Guided Pain Management and Drs. Mathis and O'Brien have pleaded it, the threshold issue is that NECC is a necessary and indispensable party to this case, thereby rendering Plaintiff's complaint defective.¹ In view of the numerous allegations concerning NECC asserted in her Complaint, without the party that manufactured and sold the contaminated Steroid at issue in this case, "complete relief among the parties cannot be afforded." Therefore, NECC is a necessary and indispensable party to this action.

There are other grounds under which Defendant IHC has demurred to Plaintiff's complaint, which are discussed in greater detail below.

FACTUAL BACKGROUND

NECC is a Massachusetts pharmacy organization that is engaged in the designing, manufacturing, compounding, marketing, distributing, and selling of pharmaceutical drugs. NECC sells the prescription drugs it manufactures and/or compounds to companies and doctors across the United States, including within the Commonwealth of Virginia. NECC manufactured and sold the contaminated methylprednisolone acetate (the "Steroid") at issue in this case. There was no way IHC, or for any of the Defendants for that matter, to know that

¹ To the extent that the Court denies IHC's demurrer with regard to the necessary and indispensable party issue on procedural grounds, *i.e.*, the better procedural vehicle is a plea in bar such that an evidentiary hearing can be had, then IHC would join in co-defendant's plea in bar that NECC is an necessary and indispensable party.

the Steroid that was injected into the Plaintiff's husband spinal canal was contaminated with bacteria or fungi. It is the bacterial and/or fungal contamination in the Steroid that ultimately led to the Plaintiff's husband's tragic death.

The U.S. Food and Drug Administration ("FDA"), the Centers for Disease Control ("CDC") and other state and federal agencies investigated the meningitis outbreak and ultimately traced the Steroids back to NECC. These agencies then investigated NECC's operations and facility, finding unclean and unsterile conditions where the Steroids were manufactured. Among other findings, NECC failed to follow the autoclaving sterilization standards and procedures in order to prevent fungal or bacterial contamination. NECC sold and distributed the Steroid to healthcare providers and related entities, like the Defendants, around the country.

NECC marketed to, sold, and delivered the Steroid to Insight Imaging-Roanoke for use as an injectable steroid that could be prescribed and administered by Drs. O'Brien and Mathis to their patients. Insight Imaging-Roanoke is a fictitious name, and is registered to Drs. O'Brien and Mathis. (Ex. A to Insight's Demurrer to Count III.) On or about September 6, 2012, Dr. O'Brien performed an epidural injection procedure on the decedent. (Complaint ¶ 41.) Neither IHC, nor Dr. O'Brien, nor any of the Defendants for that matter, knew, had reason to know, or could have known that the Steroid manufactured by NECC was contaminated. There had not been any issues with any of Insight Imaging-Roanoke or IGPM's patients getting meningitis from a steroid injection in the past. And Plaintiff has alleged none.

Plaintiff does, however, devote over 45 paragraphs in her complaint discussing NECC's drug compounding operations (Complaint ¶¶65-87), the conditions at its facility

(Complaint ¶¶102-107), that it was compounding the Steroid on a large scale in violation of federal and state law. Indeed, Plaintiff's allegations against all Defendants are essentially found in paragraph 119 of her Complaint, that: “[d]espite what Insight-Imagaing Roanoke and its employees and agents knew, or should have known, concerning NECC, they chose to purchase [the Steroid] from NECC, which is an unaccredited, sprawling compounding pharmacy that: (a) produced its drugs in the same complex as a waste facility; (b) produced the drugs in bulk batches ...; (c) did not properly sterilize the drugs; (d) did not operate with adequate quality control measures; (e) did not operate in a sterile environment; (f) did not have adequately representative samples independently tested by an FDA-approved testing facility before releasing them for distribution; (g) did not comply with USP-NF standards; and (h) violated several provisions of Virginia statutes designed to protect Virginia citizens from substandard and adulterated prescription drugs.” (Complaint ¶119.) These are allegations that can only be properly made against a pharmaceutical company. But that company is not even in this case.

Plaintiff filed her Complaint on December 27, 2012. Less than a week earlier, NECC had just filed for bankruptcy protection on December 21, 2012, in U.S. Federal Court for the District of Massachusetts, Boston Division. More significantly, however, is that Plaintiff has filed a petition as a creditor in the NECC bankruptcy case. Plaintiff filed her lawsuit without naming NECC as a party only 6 days after NECC had filed bankruptcy in Boston. Plaintiff also filed her lawsuit without naming NECC even after NECC filed a Notice of Intent to File Bankruptcy in several other cases in this court in which NECC had properly named as a defendant that involve injured plaintiffs that had been injected with contaminated steroids manufactured by NECC.

ARGUMENT

A. NECC Is An Indispensable Party

The threshold issue for the Court to decide is whether NECC is a necessary and indispensable party to this action. If it is, then the case cannot go forward without NECC. See *Asch v. Friends of Mt. Vernon Yacht Club*, 251 Va. 89, 90 (1996) (a court lacks the power to proceed with a suit unless all necessary parties are properly before the court and, if not, the matter must be dismissed); *Gray v. Virginia Secretary of Transportation*, 77 Va. Cir. 224, 227-228 (Cir. Ct. City of Richmond, 2008) (discussing Va. Sup. Ct. R. 3:12 (a) and (c) and dismissing action because necessary and indispensable party not in the action) (*citing Mendenhall v. Cooper*, 239 Va. 71, 74 (1990) (failure to join necessary and indispensable party mandates dismissal of action)).

The grounds for determining what constitutes a “necessary and indispensable party” were initially explained by the Virginia Supreme Court in *Asch*. 251 Va. at 90-91. A necessary party:

has an interest in it, either in possession or expectancy, which is likely either to be defeated or diminished by the plaintiff's claim, in such case he has an immediate interest in resisting the demand ... are necessary parties to the suit. ...a necessary party's interests in the subject matter of the suit, and in the relief sought, *are so bound up with that of the other parties*, that their legal presence as parties to the proceeding is an absolute necessity, without which the court cannot proceed.

Id.

These principles have been incorporated into the Rules of the Sup. Ct. of Virginia as Rule 3:12 (a) and (c). See *MWAA*, 77 Va. Cir. At 227-228. A necessary party is:

A person who is subject to service of process may be joined as a party in the action if (1) in the person's absence complete relief cannot be accorded among those already parties, or (2) the person claims an interest relating to the subject of the action and

is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest of the person to be joined....

Id.

That is precisely the case here. In view of the 45+ paragraphs of allegations in Plaintiff's complaint, clearly NECC's interests are at issue in this case. Moreover, in light of the fact that any and all allegations against IHC are premised upon NECC's conduct as a pharmaceutical compounding facility, conduct for which IHC and NECC could not be joint and severally liable because, for instance, IHC is not a pharmacist or the claims under the VCPA are barred by Va. Code § 59.1-199, in its absence complete relief cannot be afforded among the parties.

Further, Rule 3:12(c) further provides that, if a necessary party cannot be brought into the action, "the court shall determine whether in equity and good conscience the action should proceed among the parties before it, or should be dismissed, the absent person being thus regarded as indispensable." *MWAA* at 228 (*citing* Rule 3:12 (c)). In order to decide whether the action must be dismissed, a Court must weigh these four factors:

first, to what extent a judgment rendered in the person's absence might be prejudicial to the absent person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the persons absence will be adequate; [and] fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder.

Applying these factors demonstrates that with NECC is an indispensable party to this action. With regard to the first factor, clearly NECC is prejudiced by not being able to defend

itself in the case. Besides the repeated allegations of wrongdoing against NECC, to which it shall need to be heard from, Plaintiff is also a creditor against NECC in the bankruptcy action. NECC therefore clearly has interests of to protect in this case -- its own and that of its creditors.

All of the current Defendants would be prejudiced without NECC in this case. For instance, as further discussed below with regard to Count III, Plaintiff's claim under the Virginia Consumer Protection Act is barred because of Va. Code § 59.1-199. (The VCPA does not apply to any aspect of a consumer transaction where part of that transaction is authorized under the laws or regulations of the Commonwealth of Virginia and the United States.) Consequently, in view of the allegations against IHC that are solely premised upon the conduct of NECC, its absence from this case is clearly prejudicial to not only it, but the other Defendants as well. This first factor clearly weighs in favor that NECC is an indispensable party to this action.

With regard to the second factor, Plaintiff seeks \$25 million dollars in damages from IHC. Under the circumstances, there is no possible way to fairly and adequately issue a protective ruling to shape any relief, or other measures that IHC can think of – other than to have NECC as a party to this action – that would lessen the prejudice that would be imposed on IHC and the other defendants. This factor also clearly weighs in favor of the contention that NECC is an indispensable party.

With regard to the third factor, whether a judgment rendered in the person's absence will be adequate, as discussed in further detail below, there would not be a valid claim under the VCPA against IHC. Similarly, as discussed in further detail below under Count I, Plaintiff's claims with regard to an adulterated drug only apply to a pharmacist or pharmacy,

such as NECC. *See* Va. Code. § 54.1-3410.2(D) (it is the pharmacist, and not the treating or administering health care provider or other party involved in that process, who “shall personally perform or … supervise the compounding process, which shall include a *final* check for accuracy and conformity to the formula of the product … appropriate conditions and procedures, and appearance of the *final* product.”) (emphasis added.) IHC is not a pharmacist or pharmacy. Thus, without NECC as a defendant in this case, application of the sections of the VDCA on which Plaintiff relies cannot even apply. Accordingly, any judgment rendered in the NECC’s absence would be inadequate because Plaintiff’s certainly has claims against NECC. This factor also weighs in favor of that NECC is a necessary and indispensable party to this case.

With regard to the fourth and final factor, Plaintiff clearly has a remedy: She can amend her Complaint to name NECC as defendant in this case. The fact that they simply chose not to, and then attempt to shift that burden to the Defendants, making Defendants *de facto* plaintiffs of the third-party variety would render the nonjoinder rules meaningless.

Plaintiff concedes that in the absence of a necessary party, that an action cannot go forward. (*See* Plaintiff’s Br. At 4 citing *Siska v. Trust v. Milestone Development, LLC*, 282 Va. 169 (2011) (dismissing action for lack of necessary party). However, she then states the remedy is that IHC and the other defendants can file a third-party complaint to remedy the problem. In other words, Plaintiff seeks to avoid the rule that all necessary and indispensable parties must be in the case, and shift its burden to bring NECC into the case to the Defendants. That scenario, however, would require the Defendants to defend on one front and prosecute Plaintiff’s case on the other. But that scenario would, among other things, lead to inconsistent rulings or potentially require the Defendants to re-litigate issues with NECC in

a separate action that may have already been decided because NECC was not a party in the first place. That is not fair or just. All of this could be avoided had Plaintiff named all necessary and indispensable parties, including NECC.

Plaintiff also contends that IHC's claims against NECC are merely contribution or indemnity claims and, therefore, are not yet even ripe. But that is not true. In fact, many of the allegations asserted by Plaintiff against IHC are not claims under which IHC can be liable. For instance, Plaintiff's claims premised upon violations of the VDCA do not apply to IHC because it is not a pharmacist or a pharmacy. Likewise, with regard to her claims premised upon the VCPA, because her claims are inextricably intertwined with violations of federal and state law with regard to the manufacture and sale of pharmaceutical drugs, any such claim is barred by Va. Code § 59.1-199. Accordingly, these claims against IHC would fail under Virginia law and, therefore, could not serve as a basis for her claim that IHC is a joint tortfeasor.

Plaintiff's attempts to distinguish the cases relied upon by IHC misses the mark. The cases relied upon by IHC all demonstrate that a defective pleading should be remedied at the outset so that later on in the case, after extensive judicial time and resources have already been spent, a matter is not dismissed or stayed for lack of a necessary and indispensable party. Plaintiff's Complaint fails to name a necessary and indispensable party and, therefore, cannot go forward. It benefits all parties to this matter to have all of the necessary and indispensable parties present in the case.

B. Demurrer as to Counts I-V

1. Negligence *Per Se*

In Count I, Plaintiff contends that IHC is negligent *per se* based on a violation of various sections of Va. Code § 54.1-3400, known as the Virginia Drug Control Act or VDCA, including Va. Code § 54.1-3461(A)(2) (preparation or release of unsanitary drugs), Va. Code § 54.1-3461(B) (failing to meet purity or quality standards in drug compendium or under federal standard), and § 54.1-3457 (1) and (3) (release of impure drug into commerce and injuring patients). (Complaint ¶¶ 181-194.)

Plaintiff contends that Defendants unlawfully received and provided to Plaintiff's husband an adulterated drug as defined under Va. Code §3461(B). Under the statute, an adulterated drug is: “[a] drug or device shall be deemed to be adulterated if it purports to be or is represented as a drug the name of which is recognized in an official compendium and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination of strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act.” *Id.*

Another section of the VDCA § 54.13410.2(D), however, makes clear that it is the pharmacist's responsibility to make “*a final* check for accuracy and conformity to the formula of the product ... appropriate conditions and procedures, and appearance of the *final* product.” (emphasis added). Similarly, § 54.1-3410.2(E) provides that only the pharmacist “shall ensure compliance with the USP-NF standards for ... sterile ... compounding.”). IHC is not a

pharmacist. Instead, as the manufacturer and seller of the Steroid at issue in this case, only NECC could have performed the assay tests to determine the strength or purity of the Steroid at issue here. Similarly, only NECC could have known the purity of the Steroid it manufactured and sold and, therefore, whether it was providing an adulterated drug, instead of another approved drug under the Virginia Code. NECC provided sealed vials to the Defendants. Plaintiff has not pleaded otherwise. (See Count I.) Accordingly, the burden for ensuring the efficacy and safety of drugs under this part of the VDCA squarely falls on a pharmacist and compounding facilities, such as NECC. The VDCA therefore cannot apply to IHC under the circumstances.

Moreover, there is no stand-alone or separate cause of action for negligence *per se* under Virginia law. *See Williams v. Old Brogue, Inc.*, 232 Va. 350 (1986) (the doctrine of negligence *per se* does not exist as a stand alone claim and cannot create a cause of action where none otherwise exists). Instead, any such claim must arise from a breach of a standard of care set forth by statute. *Talley v. Danek Med., Inc.*, 179 F.3d 154, 158 (4th Cir. 1999) (“the negligence *per se* doctrine, however, is not a magic transforming formula that automatically creates a private right of action for the civil enforcement, in tort law, of every statute.”). There can be no basis for Plaintiff’s claim because the VDCA does not apply to IHC. If there can be no claim under the VDCA, then there is no statutory violation on which to base a negligence *per se* claim under Virginia law. Accordingly, Plaintiff’s negligence *per se* claim against IHC should be dismissed.

2. Virginia Consumer Protection Act

In Count II, Plaintiff alleges that the decedent and IHC engaged in a transaction involving the sale of the steroid that falls under the purview of Va. Code § 59.1-198, the

VCPA. Hence, Plaintiff contends that IHC is a “supplier in connection with a consumer transaction” as those terms are defined under the VCPA.

The VCPA does not apply to any aspect of a consumer transaction where part of that transaction is authorized under the laws or regulations of the Commonwealth of Virginia *and* the United States. Va. Code § 59.1-199. But that is precisely the case here. The formulation, compounding and sale of prescription drugs is authorized under the Food Drug Cosmetic Act, 21 U.S.C. §§ 301, *et seq.*; regulated by the Food and Drug Administration, 21 C.F.R. §§ 200, *et seq.* The compounding and sale of prescription drugs is also authorized by the Virginia Drug Control Act, §§ 54.1-3400, *et seq.* Accordingly, the manufacture and sale of compounded drugs are authorized and/or sanctioned by both federal and state statutes. It follows that Va. Code 59.1-199 bars Plaintiff’s claim under the VCPA against IHC. *See Manassas Auto Cars Inc. v. Couth*, 274 Va. 82, 90 (2007); *see also Deane v. Novacare Orthotics & Pros. East, Inc.*, 50 Va. Cir. 418, 420 (1988) (claims under the VCPA “is not the correct avenue to recover other “personal injury” damages. These damages can be, and should be recovered in a products liability case.”). Accordingly, this claim against IHC should be dismissed.

3. Negligence

The Third Count pleads negligence against IHC. For instance, the Complaint alleges that the decedent received an epidural steroid injection at “Insight Imaging-Roanoke.” (Complaint ¶158.) The Complaint further alleges that the epidural steroid injection was administered by Dr. O’Brien, an employee of “Insight Imaging-Roanoke.” (*Id.* ¶¶ 41, 42, 159). The Court may take judicial notice of the fact that the fictitious name “Insight Imaging-Roanoke” is registered to Image Guided Pain Management, P.C. *See* Va. Code

§§8.01-388 and 389; *see also Station #2, LLC v. Lynch*, 75 Va. Cir. 179, 191 (Cir. Ct. City of Norfolk, April 2008) (the court may take judicial notice of public records); *Slaughter v. Commonwealth*, 54 Va. 767, 777 (1856) (“the court would take judicial notice of private corporations created under general law, whose certificates were printed with the public acts of the Legislature”); *see also* Virginia State Corporation Commission filing for SCCID#07221021 for Insight-Imaging Roanoke attached as Exhibit A to IHC’s Demurrer; Complaint at ¶ 6. Under the circumstances, it is not sufficient for Plaintiff to group all of the Defendants together under the acronym, Insight Imaging-Roanoke, which is a separate legal entity from IHC and assert claims against all Defendants on that basis.

In addition, while Plaintiff’s Complaint alleges that a doctor-patient relationship existed between Image Guided Pain Management/Dr. O’Brien and the decedent, it fails to allege there was any such relationship between the decedent and IHC. Nor could it, since IHC is not a physician and these type of duties would not delegable as they relate to the administration of epidural injection of the Steroid. Thus, as plead, the Plaintiff’s Complaint fails to allege any facts that would support a contention that there was a duty owed by IHC to the decedent. This claim against IHC should be dismissed.

4. Gross Negligence

Plaintiff alleges a related claim for Gross Negligence in Count IV. This claim suffers from the same problem as the Negligence Count because the allegations contained in this Court are also asserted against Insight Imaging-Roanoke. (Complaint ¶¶ 217-221.) It also fails to allege that any such special relationship existed as between IHC and the decedent, or to distinguish its allegations under this Count from the duties owed under a doctor-patient relationship. For example, Plaintiff alleges that IHC “procured, received, and provided to

Mr. Wingate the epidural injection which is at issue in this case.” (Complaint ¶9.) However, Plaintiff then alleges that Insight Imaging-Roanoke did not “even meet the most minimal diligence to ensure they were not injecting adulterated and tainted drugs directly into the bodies of the patients, including Mr. Wingate.” (Complaint ¶ 219.) But IHC did not perform the epidural injection. Dr. O’Brien performed the procedure. (Complaint ¶ 41.) It is simply not enough to merely recite the elements of the cause of action that all Defendants, for instance, were “heedless and palpable,” or all acted with “such an utter disregard for prudence” in order to satisfy the pleading requirement for a gross negligence claim. *See BB&T Ins. Servs. v. Thomas Rutherford, Inc.*, 80 Va. Cir. 174, 176 (Cir. Ct. City of Richmond, Feb. 9, 2010) (formulaic recitation of the elements of a cause of action, instead of pleading actual facts, will not suffice and the court granted the demurrer as to a claim for breach of fiduciary duty); *see Frazier v. City of Norfolk*, 234 Va. 388, 393 (1987) (dismissing gross negligence claim); *Kennedy v. McElroy*, 195 Va. 1078, 1082, 81 S.E.2d 436, 439 (1954). As a result, this claim against IHC should be dismissed.

5. Fraud

Under Virginia law, a plaintiff alleging a fraud claim must assert that a false representation of material fact was made innocently or negligently by the defendant, and that the plaintiff relied on that false representation. *See, e.g., State Farm Mut. Auto. Ins. Co. v. Remley*, 270 Va. 209, 218, 618 S.E.2d 316, 321 (2005). There are neither specific allegations that IHC made a representation of any kind, intentionally or otherwise, regarding the steroids at issue to the decedent or that Plaintiff relied on any such representation before he received treatment. Instead, Plaintiff asserts as the basis of its fraud claim the billing statements and

that an insurance company may have been misled. (Complaint ¶¶223-251.) As explained below, that is not sufficient.

Plaintiff alleges, for instance, that “Insight Imaging-Roanoke and its employees and agents provided patients, such as Mr. Wingate, with written false documentation asserting that the drug injected was, in fact, the name branded drug produced by FDA-regulated manufacturer, Pfizer.” (Complaint ¶ 228.) Plaintiff further alleges that “by misrepresenting that the drug injected was obtained from an FDA-regulated manufacturer, Insight Imaging-Roanoke and its employees and agents misrepresented a material fact regarding Mr. Wingate’s treatment.” (Complaint ¶ 233.) Critically, however, what is missing is that any of the purported misrepresentations were made to Mr. Wingate *before* he received his injections. The invoice attached as Exhibit B to the Complaint was generated after his treatment. Therefore, Mr. Wingate could not have relied on any purported misrepresentation from IHC, which is not alleged to have occurred until after he received treatment.

Similarly, the allegations that an insurance company would rely on the reference to the brand name of the steroid for billing purposes cannot be imputed to Mr. Wingate to satisfy this requirement. (Complaint ¶¶ 241-243.) Any such allegations are also alleged to have occurred after he received treatment and are alleged to have been made to the insurance company, and not to Mr. Wingate. For these reasons, Plaintiff’s fraud claim against IHC, as pleaded, should be dismissed against IHC.

6. Punitive Damages

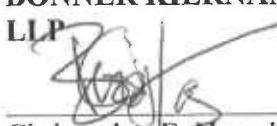
Under Virginia law, punitive damages are permitted only where there is actual malice or such gross negligence to demonstrate a conscious or willful and wanton disregard to Plaintiff’s rights. *See, e.g., Xsepedius Management Co. of Virginia, LLC v. Stephan*, 269 Va.

421, 425 (2005) (punitive damages should only be awarded in the case of the most egregious conduct); *Hogg v. Plant* 145 Va. 175 (1926). Thus, in order for there to be an award of punitive damages, at a minimum, the defendant must know that its actions would injure the plaintiff. *Doe v. Isaacs*, 265 Va. 531, 535 (2003). There was simply no way for IHC to know that NECC had provided to the Defendants a Steroid that may have caused the Plaintiff's husband's death. IHC is not a pharmacist or otherwise had any involvement in preparing the Steroid. NECC provided sealed vials of the Steroid to the Defendants. There was no warning from the CDC, the FDA, or the Virginia Department of Health with regard to NECC's operations. Accordingly, Plaintiff's claim for punitive damages against IHC should be dismissed. *Xsepedius*, 269 Va. at 425 (punitive damages should not be awarded unless there is evidence of malice, fraud, and oppression).

For the reasons stated above, defendant IHC respectfully requests the Court dismiss or, at a minimum, require the Plaintiff to amend their Complaint to remedy the defects identified herein.

Dated: February 25, 2013

BONNER KIERNAN TREBACH & CROCIATA,
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY, that I caused to be served the foregoing Reply Memorandum of Law to Plaintiff's Opposition to the Demurrer of INSIGHT HEALTH CORP. via regular mail and email this 25th day of February, 2013 to:

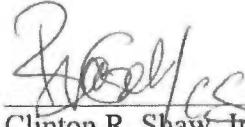
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